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SC

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/388,294 09/01/99 EVANS

M 197449000300

020350 QM12/0811  
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EXAMINER

SIRMONS, K

ART UNIT	PAPER NUMBER
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3763 S

DATE MAILED:

08/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/388,294	Applicant(s) Michael Evans
Examiner Kevin C. Sirmons	Group Art Unit 3763



Responsive to communication(s) filed on Sep 1, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

- Claim(s) 1-41 is/are pending in the application.  
Of the above, claim(s) 1-31, 40, and 41 is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 32-39 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_.  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \*Certified copies not received: \_\_\_\_\_
- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- Notice of References Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). 4  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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*Drawings*

**DETAILED ACTION**

*Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, drawn to a method for forming a second access penetration in a wall of a body lumen having a first access penetration in said wall, classified in class 604, subclass 28.
  - II. Claims 10-32, drawn to a method for positioning a guidewire in a body lumen, classified in class 604, subclass 500.
  - III. Claims 33-39, drawn to a device for positioning a filament in a body lumen, classified in class 604, subclass 164.01.
  - IV. Claims 40-41, drawn to a kit, classified in class 206, subclass 570.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination already has two separate access sites formed in the wall. The subcombination has separate utility such as forming a second access in a wall.

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*Drawings*

3. Inventions I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced by a gastronomy device.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Jim Heslin on 8/3/00 a provisional election was made without traverse to prosecute the invention of group III, claims 33-39. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-32 and 40-41 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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*Drawings*

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “support tube” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

*Claim Rejections - 35 USC § 112*

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 33-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 33 and 39, it is unclear what is the structural difference between the catheter and the support tube. They appear to be the same!

*Claim Rejections - 35 USC § 102*

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Miraki U.S. Pat. No. 5,387,193.

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*Drawings*

Miraki discloses a device for positioning a filament in a body lumen comprising: a catheter (10) which can be introduced through a first access penetration into the body lumen; and means advancable from the catheter (84) for creating a second access penetration and providing a filament path (84) between said first and second access penetrations; wherein the catheter has at least one lumen therethrough (112) and the advancable means is reciprocatable received in the catheter lumen (112); wherein the advancable means has a preformed tip which deflects laterally as it is advanced from the catheter (84); wherein the advancable means comprises a guide tube having a lumen therethrough (110) and a penetrating element removable received in the lumen and extending from the distal tip of the guide tube, wherein the penetrating means can be withdrawn from the guide tube after the guide tube has been placed between the access penetrations to leave the guide tube lumen as the filament path wherein the penetrating element is a stylet (84); further comprising an expandable anchor disposed over at least a position of the catheter (48); further comprising a support tube having a lumen (9 and 11).

*Conclusion*

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703)306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

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*LCS*

*Drawings*

Kevin C. Sirmons

Patent Examiner

8/7/00

*Sharon Kennedy  
Primary Examiner*